

REMARKS

Claims 1-44 are pending. In accordance with the foregoing, claims 1, 3, 5-7, 16, 18, 20-22, 24, 31, 34-38 and 40 are amended. Illustrative support for the amendments to independent claims 1, 16, and 31 is found in paragraph 43 of the originally-filed specification. Other claim amendments are made to correct informalities and address the Examiner's objection to claims 1-43. Claims 12-14, 27-29, 32-33, and 42-43 have been cancelled without prejudice or disclaimer of the subject matter contained therein. In the above referenced Office Action, claims 1-44 stand rejected. Reconsideration of the application is requested.

Claims 1-44 stand variously rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman (U.S. 6,004,269) in view of Niazi (U.S. 6,638,268 B2) and or further in view of Leiden (U.S. 6,297,220 B1). The present application discloses a method for locating a site along a cardiovascular system (e.g., the coronary sinus ostium) by advancing a device to an area downstream from the site (e.g., the atrium) and observing the direction of flow of a delivered contrast medium within the area and away from the site. The device can then be advanced upstream through the direction of the flow of the contrast medium into the site. The contrast medium is injected prior to advancing the device into the site. Observing the direction of flow of the contrast medium away from the site, aids in locating the site and provides guidance for advancing the device into the first site. For example, claim 1, as amended recites "delivering a contrast medium from a distal end of the delivery device within the area to locate the first site by observing the direction of the flow of the delivered contrast medium in the area away from the first site; and further advancing the delivery device upstream through the direction of the flow of the contrast medium into the first site."

Rosenman teaches guiding a catheter to the left ventricle. Once in the ventricle, a ventriculogram may be created by injecting contrast agent. The catheter tip is positioned in tissue of the left ventricle. The catheter is already in the left ventricle when the contrast agent is injected and is merely positioned at a site along the left ventricle tissue. Accordingly, observing the direction of the flow

of contrast medium delivered in an area downstream from a first site and advancing the delivery device upstream through the direction of the flow of the contrast medium into the first site is clearly not taught.

Niazi teaches advancing and rotating a catheter until the catheter slips over the tricuspid annulus, and because of the counterclockwise torque, twists and pops into the proximal coronary sinus. This manipulation is carried out in a fluoroscopic view. The use of a contrast agent to guide advancement of the catheter into the coronary sinus is not taught nor suggested. Once in the coronary sinus, a distal balloon is inflated to occlude the proximal coronary sinus. Contrast medium is injected to obtain a coronary sinus angiogram. It would be apparent to one having ordinary skill in the art that the injected contrast agent flows upstream against the direction of blood flow in the venous system in order to capture an image of the coronary sinus and cardiac vein branches. The balloon occlusion is required to prevent downstream flow of the contrast agent. A coronary sinus lead is advanced in a branch of the coronary sinus by advancing the lead, in the same direction as the injected flow of the contrast agent, to an imaged branch. Thus Niazi likewise fails to teach, suggest, or imply, observing the direction of flow of delivered contrast medium away from a site and advancing a device upstream through the direction of the flow of the contrast medium into the site.

Leiden purportedly teaches fluoroscopic-injection based guidance of a catheter into the coronary sinus ostium. Applicant respectfully traverses. Leiden teaches injection of an adenovirus vector in the coronary sinus after a catheter has been situated in the coronary sinus ostium. Leiden never mentions the use of a contrast agent for locating the coronary sinus ostium. Leiden only specifies fluoroscopic guidance. Advancing a catheter into the coronary sinus ostium using only fluoroscopic guidance, while not an impossible task, is a very difficult one since the ostium is difficult to locate. The present application addresses the difficulty of this task by teaching a method that facilitates advancement of a catheter into a coronary sinus ostium by using the direction of flow of contrast agent away from the ostium within the atrium to guide the advancement of the

catheter into the ostium upstream through the contrast agent flow. Such guidance is not taught in the prior art. Applicant respectfully asserts the pending claims would not be obvious to one having skill in the art based on the disclosures of the cited references without the benefit of the teachings of the instant application.

Applicant asserts that the remarks presented herein are fully responsive to the Office Action and are sufficient to overcome the rejections presented in the Office Action. However, there may be other arguments to be made as to why the pending claims are patentable. Applicant does not concede any such arguments by having not presented them herein. Further, Applicant reserves the right to re-present any originally filed, cancelled, and/or previously unclaimed subject matter in a subsequently filed continuing application without prejudice or disclaimer. Applicant respectfully asserts that the present claims are in condition for allowance. Withdrawal of the instant rejections and issuance of a Notice of Allowance is respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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/ Carol F. Barry/
Carol F. Barry, Reg. No. 41,600
Telephone: (763) 526-0932
Customer No. 27581